CHAPTER 83C

PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)

SUBCHAPTER 1 REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

8:83C-1.1 Introduction

This subchapter provides information about the provision of pharmaceutical services under the PAAD program which shall extend assistance to certain persons whose level of income disqualifies them for medical assistance under the Medical Assistance and Health Services Act, but who have medical needs for prescribed drugs and/or insulin, insulin needles, insulin syringes and diabetic testing materials and syringes and needles for injectable medicines used in the treatment of multiple sclerosis, and are unable to fully meet the cost of such items. For additional information regarding PAAD eligibility, see N.J.A.C. 8:83.

8:83C-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise.

"Annual income" means all income from whatever source derived, actually received or anticipated.

"Applicant" means an individual who applies for PAAD, either personally or through an authorized agent.

"Beneficiary" means an individual who has been found eligible for PAAD benefits.

"Calendar year" means a year beginning January 1 and ending on December 31. It is the base period utilized to determine annual income and PAAD eligibility.

"Centers for Medicare and Medicaid Services (CMS)" means the agency of the Federal Department of Health and Human Services, which is responsible for the administration of the Medicare program in the United States. CMS was formerly known as the Health Care Financing Administration (HCFA).

"Commissioner" means the Commissioner of the Department of Health and Senior Services.

"Current year" means the calendar year in which a person applies or reapplies for PAAD.

"Department" means the Department of Health and Senior Services.

"Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)" means a type of Medicare Part B coverage that applies to certain types of medical equipment and supplies. Pharmacies enrolling as Medicare Part B suppliers for the purpose of PAAD's Medicare Recovery initiative must enroll under DMEPOS.

"Electronic Data Interchange (EDI) Enrollment Form" means an agreement signed by a Medicare Part B Supplier authorizing PAAD to bill Medicare electronically on its behalf for claims that are eligible under both PAAD and Medicare.

"Expiration date" means the date when a beneficiary's PAAD eligibility ends.

"Initial Prescription Claim" means a PAAD claim for a drug not previously paid by the State during the 200-day calendar period immediately preceding the service date of a claim being considered for payment; or a PAAD claim that exceeds a time period based on the service date of the previously paid PAAD claim.

"Legend drug" means any approved drug product which by Federal law cannot be dispensed without a prescription and bears the statement on the label: "Caution: Federal law prohibits dispensing without a prescription."

"Medicare" means medical assistance provided to certain aged and disabled persons as authorized under Title XVIII (Medicare) of the Social Security Act.

"Medicare Part B Supplier" means a supplier of Medicare Part B (Medical Insurance) services to Medicare beneficiaries including Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

"National Supplier Clearinghouse (NSC)" means the entity that issues Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) supplier authorization numbers nationwide to Medicare Part B Suppliers for the Centers for Medicare and Medicaid Services (CMS). The National Supplier Clearinghouse is located at P.O. Box 100142, Columbia, SC 29202-3142.

"NSC Supplier Number" means the authorization number issued by the National Supplier Clearinghouse (NSC) to a Medicare Part B Supplier of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) for the Centers for Medicare and Medicaid Services (CMS).

"Pharmacy" means any pharmacy located in New Jersey, operating under a valid permit from the Board of Pharmacy of the State of New Jersey, which has filed an application and agreement of participation which has been approved by the New Jersey Medicaid Program.

"Prescription drugs" means all approved legend drugs, including any interchangeable drug products contained in the latest list approved and published by the Drug Utilization Review Council in conformance with the provisions of the "Prescription Drug Price and Quality Stabilization Act," and insulin, insulin syringes, insulin needles and certain diabetic testing materials when prescribed.

1. The term "prescription drugs" includes:
    i. Any drug product which by Federal law cannot be dispensed unless ordered by a physician, dentist or podiatrist;
    ii. Every product considered to be a legend prescription drug which is required by the Federal Food, Drug and Cosmetic Act to have the following statement on the manufacturer's original packaging label: "Caution: Federal law prohibits dispensing without a prescription";
    iii. Insulin, insulin syringes and insulin needles. While not legend drugs, these items are covered by this program when prescribed;
    iv. Diabetic testing materials including blood glucose reagent strips which can be visually read, urine monitoring strips, tapes and tablets and bloodletting devices and lancets (electronically monitored devices are not included); and
    v. Syringes and needles for injectable medicines for the treatment of multiple sclerosis.
2. The term "prescription drugs" excludes cosmetic drugs as indicated at N.J.A.C. 8:83C-1.15 unless medically necessary.

"Previous year" means the calendar year preceding the year in which the person is applying or reapplying for PAAD. For example, 1995 is the "previous year" when referring to an application which is dated between January 1, 1996 through December 31, 1996, inclusive.

1. If a person, who is required to submit a Federal, State and/or City Income Tax return, applies for PAAD at the beginning of a calendar year but has not yet filed an income tax return for the previous year, the last year for which the person filed a tax return is considered to be the "previous year" when completing the PAAD application.

"Provider" means any individual, partnership, association, corporation, institution, or any other public or private entity, agency, or business concern, meeting applicable requirements and standards for participation in the New Jersey Medicaid Program, and the Pharmaceutical Assistance to the Aged and Disabled Program, and where applicable, holding a current valid license, and lawfully providing medical care, services, goods and supplies authorized under N.J.S.A. 30:4D-1 et seq. and amendments thereto.

"Refill Prescription Claim" means a PAAD claim for a previously paid prescription in which the time period between claims is less than or equal to two times the days supply reported by the previously paid PAAD claim for the same prescription. A refill prescription claim may have the same or different prescription number.

"Resident" means "one legally domiciled within the State (of NJ) for a period of 30 days immediately preceding the date of application for inclusion in the PAAD Program. Mere seasonal or temporary residence within the State, of whatever duration, does not constitute domicile." (See N.J.A.C. 8:83-6.4 for residence requirements.)

8:83C-1.3 Participation of eligible providers

(a) A pharmacy, with a retail or institutional permit, may participate in the PAAD program as a provider of pharmaceutical services.

(b) To be approved as a provider of pharmaceutical services, the pharmacy shall:

1. Operate under a valid retail and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey. A pharmacy operating under an out-of-State retail or institutional pharmacy permit may not participate as an approved provider in the PAAD program.
2. File an application and sign an agreement with the Department of Human Services (DHS), Division of Medical Assistance and Health Services (DMAHS).
    i. All new PAAD/Medicaid provider applications from a prospective PAAD pharmacy provider (Form FD-29) shall list the pharmacy's NSC Supplier Number or include a statement that the pharmacy has applied for a NSC Supplier Number. Proof of the assigned NSC Supplier Number or of application for a NSC Supplier Number as listed in (c) below shall be provided with the application.

ii. Upon sale or other change of ownership of an approved pharmacy, the agreement is automatically terminated. To execute a new agreement to participate in the PAAD program, the new owner(s) shall apply to the Division of Medical Assistance and Health Services, Department of Human Services, by contacting the Medicaid Provider Enrollment Unit (see N.J.A.C. 10:49, Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit.

3. To enroll as a Medicaid provider of pharmaceutical services, a pharmacy shall contact the Fiscal Agent Provider Enrollment Unit (see N.J.A.C. 10:51, Appendix D, Fiscal Agent Billing Supplement).

4. Establish and maintain active enrollment as a Medicare Part B DMEPOS Supplier, provide proof of such enrollment to PAAD, an authorized PAAD to bill eligible claims electronically on the pharmacy's behalf as a billing agent for those claims that are dually eligible for both PAAD and Medicare (see N.J.A.C. 8:83C-1.4, Medicare recovery initiative).

(c) To ensure continued enrollment as a PAAD-participating pharmacy, a pharmacy shall:

1. Establish and maintain active enrollment as a Medicare Part B DMEPOS Supplier by obtaining a NSC Supplier Number from the National Supplier Clearinghouse (NSC) or other appropriate agent of the Centers for Medicare and Medicaid Services (CMS);

2. Provide proof of such enrollment to PAAD in the form of either:

i. A copy of a recent Medicare Part B remittance letter, with the NSC Supplier Number clearly indicated;

ii. A copy of a recently submitted original CMS1500 claim form, with the NSC Supplier Number clearly indicated;

iii. A copy of the approval letter from NSC containing the assigned NSC Supplier Number; or

iv. If an approval letter has not yet been received from NSC, a copy of the completed application form CMS 855s can be submitted to show that a good faith effort is being made to obtain a NSC Supplier Number;

3. Complete and return an EDI Enrollment Form, included with the provider enrollment packet, authorizing PAAD to bill Medicare electronically for eligible claims; and

4. Comply with Medicare dispensing and documentation requirements as described in Medicare's Supplier Manual.

8:83C-1.4 Medicare recovery initiative

(a) PAAD beneficiaries are required to authorize assignment of benefits to the State of New Jersey for any plan of assistance or insurance that covers the cost of prescription drugs at least in part. (See N.J.A.C. 8:83-6.9, Authorization.) The Medicare Recovery initiative was established to allow PAAD to recoup the cost of prescription drug benefits payable under Medicare Part B.

(b) All New Jersey pharmacies that participate in the PAAD program are mandated to comply with the requirements of the Medicare recovery initiative as a condition of continued participation.

1. Pharmacies shall enroll as Medicare Part B DMEPOS suppliers and maintain active status. Proof of Medicare enrollment shall be supplied to PAAD as described in N.J.A.C. 8:83C-1.3(c) 2.
2. Pharmacies shall comply with all Medicare documentation requirements as described in the Medicare Supplier Manual, including ensuring that the patient's diagnosis code is recorded by the doctor on every Medicare-eligible written order, and retaining records for the specified period of time.

(c) Recoupment of PAAD's expenditures for Medicare eligible drugs and supplies is made using the following procedures:

1. When pharmacies submit claims to PAAD, the point-of-sale system identifies those claims that are potentially eligible for reimbursement by Medicare. The pharmacy is notified to maintain Medicare documentation requirements for these claims via an edit code returned by the system.
2. PAAD, acting as a billing agent for the pharmacies under 42 C.F.R. § 424.73, submits eligible claims to Medicare.
3. Medicare pays its allowable amount for eligible claims directly to the pharmacies.
4. PAAD collects the reimbursement by withholding the amount of the Medicare payments from future PAAD remittances.

8:83C-1.5 Conditions for participation as a provider of pharmaceutical service

(a) All participating pharmacies shall provide complete prescription services, including injectables and injectable anti-neoplastic agents, compounding, and prescription refill services, when allowable. Prescriptions must be dispensed in compliance with all current existing Federal and State laws.

(b) All drugs must be prescribed.

1. “Prescribed drugs" means simple or compounded substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are:
   ii. Dispensed by licensed pharmacists in accordance with regulations promulgated by the New Jersey State Board of Pharmacy, N.J.A.C. 13:39; and additional prescription pricing in accordance with P.L. 1994, c.67, as revised by P.L. 1995, c.5 (see N.J.A.C. 8:83C-1.15(b)); and
   iii. Dispensed by licensed pharmacists on the basis of a written prescription that is recorded and maintained in the pharmacist's records.

(c) Participating pharmacies shall permit properly identified representatives of the Division of Medical Assistance and Health Services or Department of Health and Senior Services (DHSS) to:

1. Inspect written prescriptions on file;
2. Audit records pertaining to covered persons;
3. Inspect private sector records, where deemed necessary to determine a pharmacy's usual and customary charges to the public;
   i. Information pertaining to the patient's name, address, and prescriber will remain confidential within the limits of the law. Only the following items may be reviewed:
      (1) Drug name;
      (2) Quantity dispensed;
      (3) Price;
      (4) Prescription number (for reference purposes only); and
      (5) Date dispensed.
   ii. The pharmacy shall provide sufficient information with regard to its contractual agreement(s) and payment history with other private third party prescription plans to identify and verify number of claims, amount paid, and dispensing fee

paid by group contracts within the plan. Records and contracts shall be available onsite at the time of audit; or available within 10 working days of an on-site audit. Records shall include, but not be limited to:

(1) Payment vouchers;

(2) Contracts; and

(3) Agreements; and

4. Inspect records of purchases of covered drugs for which claims have been made for reimbursement.

8:83C-1.6 Program restrictions affecting payment for prescribed drugs

(a) The choice of prescribed drugs shall be at the discretion of the prescribed within the limits of applicable laws. However, the prescriber's discretion is limited for certain drugs. Reimbursement may be denied if the requirements of the following rules are not met:

1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 8:83C-1.14 and 1.15, respectively;

2. Quantity of medication (see N.J.A.C. 8:83C-1.16);

3. Pharmaceutical services requiring pharmacist intervention as part of the PAAD Prospective Drug Utilization Review (PDUR) program (see N.JA.C. 8:83C-1.28);

4. Dosage and directions (see N.JA.C. 8:83C-1.17);

5. Telephone-rendered original prescriptions (see

N.J.A.C. 8:83C-1.18);

6. Changes or additions to the original prescription (see N.J.A.C. 8:83C-1.19);

7. Prescription refill (see N.JA.C. 8:83C-1.20);

8. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.JA.C. 8:83C-1.21);

i. Products listed in the current New Jersey Drug Utilization Review Council (DURC) Formulary (hereafter referred to as "the Formulary"), and all subsequent revisions, distributed to all prescribers and pharmacists; and

ii. Non-Proprietary or generic dispensing (see N.J.A.C. 8:83C-1.12);

9. Federal regulations (42 C.F.R. 447.301, 331-333) that set the aggregate upper limits on payment for certain multi-source drugs if Federal Financial Participation (FFP) is to be made available. The limit applies to all "maximum allowable cost" drugs (see N.JA.C. 8:83C-1.7, Basis of payment); and

10. Drug Efficacy Study Implementation (DESI):

    "Less than effective drugs" subject to a Notice of Opportunity for Hearing (NOOH) by the Federal Food and Drug Administration (see N.J.A.C. 8:83C-1.22) and listing of DESI drugs in (N.JA.C. 10:51, Appendix A).

8:83C-1.7 Basis of payment

(a) This section provides a summary of the elements involved in the calculations of the payment of legend or certain non-legend drugs. The elements include the following:

1. Program restrictions affecting reimbursement for the dispensing of drugs as listed in N.J.A.C. 8:83C-1.6;

2. Price information as supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division of Medical Assistance (Medicaid) as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The drug price shall not exceed the lower of the average wholesale price minus 10 percent as supplied by the reference drug file contractors; the provider's usual and customary charge; or the drug's maximum allowable cost, if applicable (see (b) below);

    i. The NJMMIS reference drug file is updated periodically by the fiscal agent based upon data supplied by First Data Bank (FDB). The update process provides the fiscal agent with current data to include changes in product description. Providers are made aware of therapeutic indications for various classes of drugs by product literature distributed by drug manufacturers and by various trade publications. Based on market information, providers can determine whether a product's therapeutic classification meet the criteria specified in N.J.A.C. 8:83C-1.14, Covered pharmaceutical services.

3. Federal regulations (42 CFR 447.301, 331-333) that set the aggregate upper limits on payment for certain covered drugs in the pharmaceutical program. The New Jersey Medicaid program refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. Provider's usual and customary charge for legend drugs (see (c) below), insulin, insulin needles and syringes, or diabetic testing materials.

(b) Payment for legend drugs is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). See N.J.A.C. 10:51, Appendix B, for the listing of MAC drugs.

1. Maximum allowable cost is defined as:

   i. The MAC price for listed multi-source drugs published periodically by the Health Care Financing Administration (HCFA) of the United States Department of Health and Human Services; or

   ii. For legend drugs not included in (b) 1i above, the Estimated Acquisition Cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus regression category or discount.

2. For information about the "regression categories and discounts," see N.J.A.C. 8:83C-1.8 and for usual and customary charge, see N.J.A.C. 8:83C-1.13.

3. If the published MAC price as defined in (b)1i above is higher than the maximum allowable cost which would be paid as defined in (b)1ii above, then (b)1ii above shall apply.

(c) The maximum charge to the PAAD program for drugs, including the charge for the cost of medication and the dispensing fee, shall not exceed the provider's usual and customary and/or posted or advertised charge.

(d) The maximum allowance for the non-legend drugs, devices, or supplies under the PAAD program, for claims with service dates prior to July 15, 1996, shall be:

1. The product's AWP plus 50 percent; or

2. The usual over-the-counter (OTC) retail price charged to the other persons in the community, whichever is less.

(e) For claims with service dates on or after July 15, 1996, the maximum allowance for non-legend drugs, devices, or supplies under the New Jersey Medicaid program shall be calculated in accordance with (b)1ii above.

(f) For claims with service dates on or after July 15, 1996, the maximum cost for each eligible prescription claim not covered by the Maximum Allowable Cost price, as defined in (b)1i above, shall be based on the Average Wholesale Price (AWP) of a drug, as defined in (b) 1ii above, less a discount of 10 percent.

8:83C-1.8 Regression categories and discounts

(a) For pharmaceutical services provided prior to July 15, 1996, the maximum cost for each eligible prescription claim not covered by the maximum allowable cost price (see N.J.A.C. 8:83C-1.7, Basis of payment) shall be subject to the following fiscal conditions based upon six categories. The category, as determined by the New Jersey Medicaid program, is based on the previous year's total prescription volume for each participating pharmacy. The categories shall be reviewed annually and adjusted as appropriate.

1. Those pharmacy providers who have been in business for less than one calendar year shall have their prescription volume projected for the entire year, to determine the appropriate category.

(b) For pharmaceutical services provided prior to July 15, 1996, the pharmacy provider shall submit, in writing, an annual report on form FD-70 (See N.J.S.A. 10:51, Appendix C, Pharmacy Provider Certification Statement) certifying its prescription volume. The Division of Medical Assistance (Medicaid) shall determine a provider's total prescription volume, which includes all prescriptions filled (both new and refills), including nursing facility prescriptions, for private patients, Medicaid, PAAD, and other third party recipients for the previous calendar year. Failure to submit this report annually shall result in the provider being placed in the maximum discount category (category VI) for the year of non-compliance, or until the required report is received.

1. Category I: Pharmacies whose total prescription volume in the preceding calendar year was not more than 14,999 prescriptions.
    i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.JA.C. 8:83C-1.7, Basis of payment, as the maximum.
2. Category II: Pharmacies whose total prescription volume in the preceding calendar year was at least 15,000 but not more than 19,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.7, less three percent, as the maximum.

3. Category III: Pharmacies whose total prescription volume in the preceding calendar year was at least 20,000 but not greater than 29,999 prescriptions.

   i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.7, less three percent, as the maximum.

4. Category IV: Pharmacies whose total prescription volume in the preceding calendar year was at least 30,000 but not greater than 39,999 prescriptions.

   i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.7, less four percent, as the maximum.

5. Category V: Pharmacies whose total prescription volume in the preceding calendar year was at least 40,000 but not greater than 49,999 prescriptions.

   i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.7, less five percent, as the maximum.

6. Category VI: Pharmacies whose total prescription volume in the preceding calendar year was at least 50,000 prescriptions or more.

   i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.7, less six percent, as the maximum.

   ii. For pharmacies with a total prescription volume, in the preceding calendar year of 50,000 prescriptions or greater, completion of the portion of the FD-70 Certification Statement is optional. For these pharmacies a maximum regression shall be automatically applied.

7. The appropriate calculated discount shall be automatically deducted, regardless of prescription cost, by the fiscal agent, from the cost of each covered drug or device during claim processing by the New Jersey Medicaid Management Information System (NJMMIS).

(c) For claims with service dates on or after July 15, 1996, the discount is 10 percent for each eligible prescription claim not covered by the Maximum Allowable Cost price.

8:83C-1.9 Prescription drug dispensing fee

(a) The dispensing fee for each prescription, dispensed by providers having retail permits to recipients other than those in nursing facilities, is $3.73. Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following:

1. Twenty-four hour emergency service: $0.11. The provider shall have a 24-hour per day, 365 days per year prescription service available and shall have provided PAAD beneficiaries opportunities to utilize this service.
2. Patient consultation: $0.08. In addition to routinely monitoring recipient profiles for drug interactions, contra-indications, allergies, etc., the provider shall, where appropriate, discuss the course of drug therapy with the recipient. This discussion must include emphasis on compliance with the prescriber's orders; proper drug utilization; cautions about possible side effects; foods to avoid; proper drug storage conditions; and any other information that will prove beneficial to the recipient while on drug therapy.
3. Impact area location: $0.15. The provider shall have a combined Medicaid and PAAD prescription volume equal to or greater than 50 percent of the provider's total prescription volume.
    i. The nursing facility prescription volume shall be included for the determination of total prescription volume in determining entitlement to the impact allowance.

(b) Price information is supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The calculated price shall not exceed the lower of the average wholesale price (AWP) or the Federal Fund Participation Upper Limit (FFPUL) as supplied by the reference drug file contractor.

(c) In order to receive any or all of the above increments, the provider shall certify annually to the Division on Form FD-70, that the services(s) as defined in (a) above, are being provided and/or that the provider is entitled to the impact increment as defined in (a) above.

1. Each claimed increment is subject to audit and retroactive recovery with appropriate penalties, if warranted, if the PAAD program determines that the provider was not entitled to reimbursement for them.

(d) Failure to submit this report annually shall result in retail pharmacy provider payments based on the basic dispensing fee of $3.73.

8:83C-1.10 PAAD program co-payment

(a) Beneficiaries in the PAAD program are responsible for a part of the cost of drugs and devices covered by the PAAD program. At the point of sale, a PAAD beneficiary shall render to a pharmacy provider a fixed or adjustable copayment of an amount determined appropriate by the Legislature (see N.J.A.C. 8:83C-1.21(a)4).

(b) A co-payment shall be rendered to a pharmacy provider for each original or refill prescription dispensed. The provider's usual and customary charge billed to the PAAD program shall be inclusive of the copayment amount which will be deducted by the New Jersey Medicaid Management Information System (NJMMIS).

1. Under no circumstances is the required rendered copayment amount to be waived for reasons of promotion, advertisement and/or competitive considerations. Failure to comply with PAAD program copayment requirements may result in a suspension of a provider's approval to participate in the PAAD program.

(c) The beneficiary co-payment amount shall not be affected by a claim's eligibility for submission to Medicare for reimbursement (see N.J.A.C. 8:83C-1.4, Medicare recovery initiative).

8:83C-1.11 Compounded prescriptions

(a) Compounded prescriptions may be reimbursed by the PAAD program. Compounded prescriptions are extemporaneously prepared mixtures of an active ingredient or ingredients and/or a pharmaceutical excipient or excipients and are dispensed by approved providers.

1. Acceptable pharmaceutical excipients which do not contribute therapeutically to a compound, include, but are not limited to hydrophilic ointment, petrolatum, aquifer, eucerin cream, phenol, menthol, resorcinol, caffeine, talc, simple syrup, aromatic elixir, distilled water, and glycerin.

(b) Claims for compounded prescriptions may be manually or electronically submitted to the fiscal agent through a point-of-sale (POS) claim adjudication system approved by the PAAD program. (See N.JA.C. 8:83C-1.27).

1. A compounded prescription is indicated by the provider by the use of the "compound drug" indicator field on a manual claim or in a similar field in the EMC claim format.

(c) Reimbursement for compound prescriptions shall not exceed the lower of:

1. The cumulative cost of the active ingredient(s), as described in N.J.A.C. 8:83C-1.7, and/or pharmaceutical excipient(s), plus a dispensing fee, as described in N.J.A.C. 8:83C-1.9; or
2. A provider's usual and customary charge.

(d) For compounded prescriptions without an active ingredient(s), reimbursement is based on the cumulative cost of the pharmaceutical excipient(s).

1. For pharmaceutical excipients costing less than $0.25, the provider may charge PAAD $0.25 for each ingredient.
2. Reimbursement for compounded prescriptions without an active ingredient(s) shall be provided under a common drug code assigned by DMAHS.

(e) Reimbursement for compounded prescriptions submitted manually or as an EMC claim is calculated based on the ingredient cost, as described in N.JA.C. 8:83C-1.7, of the most costly active ingredient, plus a dispensing fee, as described in N.J.A.C. 8:83C-1.9.

1. For compounded prescriptions without an active ingredient(s), reimbursement is based on (d) above, plus a dispensing fee, as described in N.J.A.C. 8:83C-1.9.

(f) The maximum charge for a compounded prescription must not exceed the limits set forth in N.J.A.C. 8:83C-1.16.

(g) Restrictions on payments for compounded prescriptions are as follows:

1. All legend ingredients which are contained in compounded prescriptions must be covered by the PAAD program. If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 8:83C-1.22) drug, the compounded prescriptions are not covered.

2. Compounded prescriptions containing drugs not eligible for reimbursement under N.JA.C. 8:83C-1.15 are not covered.

8:83C-1.12 Non-proprietary or generic dispensing

When medication is prescribed by its non-proprietary or generic name, the pharmacist shall dispense the least expensive, therapeutically effective equivalent product available, preferably one listed in the DURC Formulary. The labeler code and drug product code of the actual product dispensed must be reported on the claim form. The package size code reported may differ from the stock package size used to fill the prescription.

8:83C-1.13 Provider's usual and customary charge or advertised charge

(a) The provider's usual and customary charge or advertised charge is an element considered in the calculation of the basis of payment for legend drugs (see N.J.A.C. 8:83C-1.7, Basis of payment).

(b) The usual and customary charge to the PAAD program is defined as the amount a provider charges the general public for a prescription for the same drug product (same NDC number) in the same quantity as the prescription being dispensed to a PAAD beneficiary. "Usual and customary charge" means the actual charge made to the majority (51 percent) of the total patient population served by the individual pharmacy.

1. The provider shall not charge the Program more than would be charged to a cash customer when the general public, including private third party plans, accounts for more than 50 percent of a provider's total prescription volume.

    i. In the event Medicaid and/or PAAD represent more than 50 percent of a provider's total prescription volume, then, for reimbursement purposes, the provider's usual and customary charge may be considered the amount the Program would reimburse for the same services.

8:83C-1.14 Covered pharmaceutical services

(a) All covered pharmaceutical services shall be provided within the scope of the Medicaid or PAAD programs, and billed to the fiscal agent on the claim form or other approved billing method (see N.J.A.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement).

(b) Covered pharmaceutical services include:

1. Prescribed legend drugs (for their medically accepted indication) as defined in Section 1927(k)(6) of the Social Security Act. "Legend drugs" mean those drugs whose labels include the legend statement "Caution: Federal Law Prohibits Dispensing Without a Prescription."

2. Non-legend drugs, as follow:

    i. Diabetic testing materials;

    ii. Insulin needles and/or syringes;

    iii. Insulin; and

    iv. Syringes and needles for injectable medicines for the treatment of multiple sclerosis.

8:83C-1.15 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions are not covered under the PAAD program:

1. Prescriptions which are not for medically accepted indications as defined in Section 1927(k)(6) of the Social Security Act;

2. Drug products for which adequate and accurate information is not readily available, such as, but not limited to, product literature, package inserts and price catalogues;

3. Experimental drugs;

4. Medication furnished by a prescriber or an employee of a prescriber;

5. Medication prescribed for hospital inpatients;

6. Non-legend drugs other than diabetic testing materials; insulin; and insulin needles and/or syringes;

7. Prescriptions written and/or dispensed with nonspecific directions;

8. Food supplements, milk modifiers, infant formulas, therapeutic diets, special liquid or powered diets used in the treatment of obesity;

9. Drug products for which final orders have been published by the Food and Drug Administration, withdrawing the approval of their new drug application (NDA);

10. Drugs or drug products not approved by the Food and Drug Administration, when such approval is required by Federal law and/or regulation;

11. Radiopaque contrast materials (for example, Telepaque);

12. Drugs for which Federal Financial Participation (FFP) is not available, including:

    i. Drug Efficacy Study Implementation (DESI) drugs and identical, similar and related drugs (see N.J.A.C. 8:83C-1.22);

13. Any bundled drug service, except drug product cost which is a component of a bundled drug service (see N.J.A.C. 8:83C-1.23);

14. Preventive vaccines, biologicals and theraputic drugs distributed to hospital clinics and/or community health centers by the New Jersey Department of Health and Senior Services; and

15. If the provider has a delivery service, he or she may waive or discount delivery charges to the recipient but is prohibited from charging more than his or her usual and customary charge to the general public for delivery.

(b) Otherwise reimbursable products shall be excluded from payment, under the following condition(s):

1. Products whose costs are found to be in excess of defined costs outlined in N.J.A.C. 8:83C-1.7, Basis of payment;

2. Covered diabetic testing materials which do not offer significant price and/or therapeutic advantage. The criteria shall be cost and improvement in accuracy over existing reimbursable products. Therapeutic advantage (in the case of diabetic testing materials, improvement in accuracy) shall be determined by evaluation of literature and/or cost effectiveness data submitted in support of a request for admission of a diabetic testing material for inclusion in the list of reimbursable products;

3. Manufacturers and distributors may request the review of a denial of reimbursement for products under this subsection by providing supportive information not previously submitted, within 30 days of the date of the denial. Agency decision after review of support material is final;

4. Drug products available in unit-dose packaging and dispensed to residents in a boarding home or residential care setting or other community-type setting. Other community-type setting shall not include certain assisted living settings, including assisted living residency (ALRs), comprehensive personal care homes (CPCHs) and alternative family care (AFC) homes licensed by the Department of Health.

5. A prescription refilled too soon as described in N.J.A.C. 8:83C-1.20(a)5;

6. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the PAAD program. (See N.J.A.C. 8:83C-1.28);

7. Prescriptions dispensed with service dates on and after July 1, 1995, without the usual price charged by the pharmacy to other persons in the community at the time of purchase prominently displayed on the prescription receipt.

   i. This requirement shall not apply to prescriptions dispensed to PAAD beneficiaries residing in nursing facilities or residential care facilities.

   ii. The requirements contained in this paragraph (b)7 shall expire on July 1, 1998; and

8. Cosmetic drugs including drugs used in the treatment of baldness, age spots and weight loss unless medically necessary. The MEP specified at N.J.A.C. 8:83C-1.29 shall be followed to confirm medical necessity.

8:83C-1.16 Quantity of medication

(a) Public Law 1998, c.124 establishes different days supply requirements for pharmacy claims based on the drug use history of a PAAD beneficiary. Days supply limitations for an Initial Prescription Claim for PAAD beneficiaries shall be different from days supply limitations for a Refill Prescription Claim.

1. The following days supply limitations shall apply to PAAD claims:

   i. The days supply limitation for an Initial Prescription Claim shall be limited to a 34-day supply; and

   ii. The days supply limitation for a Refill Prescription Claim shall be limited to a 34-day supply or 100 dosage units, whichever is greater.

(b) Any medication continuously prescribed regardless of the frequency of administration for a period of 14 days or more shall be considered a maintenance medication.

(c) The pharmacist shall dispense the full quantity of medication prescribed within the limitations described in (a) above.

(d) Prescriptions shall not be split or reduced in quantity, unless the quantity prescribed exceeds Program limits, in which case the quantity shall be reduced to Program limits described in (a) above.

1. Exception: When the full quantity prescribed (within Program limits) is not available when a prescription is ready to be dispensed, the pharmacist shall retain the claim form or submit an EMC claim after the balance of the medication is dispensed. The pharmacist may dispense the quantity available and shall notify the beneficiary accordingly.

2. When the item prescribed is packaged from the manufacturer in quantities higher than PAAD limits, PAAD will waive the 34-day requirement limit for the reimbursement and allow the prepackaged quantity.

(e) The quantity of medication dispensed shall not be affected by a claim's eligibility for submission to Medicare for reimbursement, except where Medicare dispensing guidelines allow a greater than 34-day supply for an initial prescription and the item being dispensed is packaged from the manufacturer in quantities consistent with Medicare dispensing guidelines. In such cases, PAAD will waive the 34-day limit and follow Medicare dispensing guidelines (see N.J.A.C. 8:83C-1.4, Medicare recovery initiative).

8:83C-1.17 Dosage and directions

(a) Dosage and directions for use shall be indicated on all prescriptions. Prescriptions written and dispensed with no specific directions, such as "pm," "as directed" or "ad lib," etc. are not eligible for reimbursement. Specific directions such as "1 tablet 4 times a day PRN" are required.

1. Exceptions:
   i. Topical preparations including ophthalmic and optic drops and ointments;
   ii. Aerosol inhalers; and
   iii. Nitroglycerin.
2. For all oral medication and injectables, the number of days the medication should last, based on the prescriber's directions of use, shall be entered in the "Days Supply" field on the pharmacy claim form or similar field in the EMC claim format.

(b) The number of days reported for the days supply dispensed on the pharmacy claim or in the appropriate field on the EMC claim must accurately reflect the intended duration of drug utilization, or a reasonable estimation by the

dispensing pharmacist of a drug's intended duration of use when a drug's dosage is unrelated to a specific days supply.

8:83C-1.18 Telephone-rendered original prescriptions

(a) Telephone orders from prescribers for original prescriptions shall be permitted in accordance with all applicable Federal and State laws and regulations.

(b) For purposes of reimbursement, telephone authorization to refill an original prescription with no refill remaining is considered a new order and requires a new written prescription with a new prescription number. Stamping or writing a new number on the original prescription order does not constitute a new prescription under the PAAD program.

(c) When a prescriber chooses not to allow product interchange on a telephone order, the statement "Substitution not permitted by prescriber-telephoned Rx" plus the pharmacist's full signature next to or below the statement, shall appear on the prescription order. A rubber stamp bearing the statement is acceptable.

8:83C-1.19 Changes or additions to the original prescription

Changes or additions to the original prescription, when approved by the prescriber, shall be clearly indicated (including date and time) and signed by the dispensing pharmacist. No changes (for example, dosage, quantity, number or refills, days supply, etc.) are permitted on the original prescription order after the claim is submitted for payment.

8:83C-1.20 Prescription refill

(a) The provider shall submit a properly completed claim form or electronic claim in the proper EMC claim format to the fiscal agent for reimbursement of an allowable refill. An allowable refill shall comply with the following instructions in order to be reimbursed as such:

1. Refill instructions must be indicated in writing by the prescriber on the original prescription or verbally when telephoning the original prescription to the pharmacist. Verbal instructions shall be reduced to writing by the pharmacist, in accordance with N.J.S.A. 45:14-14.
2. The original prescription is valid for the 12 month period beginning with the date of the original prescription. There is no limit to the number of refills dispensed during the 12 month period.
    i. Exception: Oral contraceptives originally prescribed for three ovulatory cycles may be refilled up to three times within one

year if so indicated by the prescriber on the original prescription.

3. Refill instructions indicating "refill prn" or indicating more than five refills, shall be subject to the limits imposed in (a)2 above, and shall be reimbursed up to these limits only.

4. A telephone authorized refill for a prescription with no refill remaining must be assigned a new prescription number.

5. Prescription refills shall not be dispensed until a reasonable quantity (approximately 75 percent) of the medication originally dispensed or refilled could have been consumed in accordance with the prescriber's written directions for use.

   i. Exception: When a prescription is lost or destroyed, requiring a replacement prescription to be dispensed before the original prescription could have been consumed in accordance with the prescriber's written directions for use, an original pharmacy claim with written justification must be submitted to the fiscal agent for payment consideration.

8:83C-1.21 Prescription Drug Price and Quality Stabilization Act

(a) The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., shall apply to the PAAD program. This law requires that every prescription blank contain the statements "Substitution Permissible" and "Do Not Substitute." The prescriber shall initial one of the statements in addition to signing the prescription blank.

1. When the prescriber does not initial "Substitution Permissible" or the "Do Not Substitute" statement on a prescription for a drug product listed in the DURC (reference here to where it is defined) Formulary, the pharmacist shall substitute from the list of interchangeable products and bill PAAD accordingly.

2. When the prescriber initials "Substitution Permissible," the pharmacist shall dispense and bill PAAD for one of the less expensive products listed in the DURC Formulary as interchangeable with the brand name prescribed.

3. When the prescriber orders by generic name, the formulary does not apply. The pharmacist shall dispense the least expensive, therapeutically effective product available to him/her at the time of dispensing. The product is not required to be from the list of interchangeable products.

4. Whenever the prescriber does not specify that substitution is not permitted and an interchangeable drug product that is listed in the

latest issue of the formulary is available for the prescription written, the PAAD program shall reimburse the pharmacy only for the maximum allowable cost of the interchangeable product, less the PAAD program co-payment. In this case, the PAAD beneficiary can choose to either:

5. For non-MAC drugs (see N.J.A.C. 8:83C-1.7), when the prescriber initials "Do Not Substitute," the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form or the similar field in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC), as defined in N.J.A.C. 8:83C-1.7 (see N.JA.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement for instructions about the claim form or N.JA.C. 10:51, Appendix E, incorporated herein by reference, regarding the proper EMC claim format).

6. Claims for MAC drugs with service dates on or after July 15, 1996, and in those situations in which a prescriber authorizes, in accordance with (b) below, the dispensing of a brand drug, the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form, or similar field in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC), (see N.J.A.C. 8:83C-1.7) plus applicable dispensing fee or the usual and customary charge, whichever is less for the product (see N.J.A.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement for instructions about the claim form or N.J.A.C. 10:51, Appendix E, incorporated herein by reference, regarding the proper EMC claim format).

(b) Federal regulations at 42 C.F.R. 447.331 prescribe the aggregate upper limit, or Maximum Allowable Cost (MAC) for certain legend drugs which are applied to Medicaid covered pharmacy services (see (d) below). For claims with service dates on or after July 15, 1996, these limits shall apply to all MAC drugs (see N.J.A.C. 10:51, Appendix B, incorporated herein by reference) covered by PAAD unless the prescriber indicates in his or her own handwriting on each written prescription or follow-up written prescription to a telephone-rendered prescription (see N.J.A.C. 8:83C-1.7) the phrase "Brand Medically Necessary." The Federal regulation at 42 C.F.R. 447.331 requires a written statement and does not permit the use of alternatives such as a check-off box initials or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a handwritten statement "Do Not Substitute." For purposes of reimbursement, the physician's override capability under N.J.SA. 24:6E-1 does not apply to drugs which have a Federal MAC limit.

(c) For claims with service dates on or after July 15, 1996, a blanket authorization denying substitutions shall not be permitted. Each prescription order shall state "Brand Medically Necessary" in the prescriber's own handwriting. For non-MAC drugs, each prescription order shall follow the requirements of N.J.S.A 24:6E-1 et seq. (see (a) above).

(d) The dispenser must always report the actual labeler code and drug product code of the drug dispensed. The package size code reported may differ from the stock package size used to fill the prescription.

8:83C-1.22 Drug Efficacy Study Implementation (DESI)

(a) "Less than effective drugs" are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1. Reimbursement is not available for the purchase or administration of any drug product that meets all of the following conditions:
    i. The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962;
    ii. The drug product is available only through prescription;
    iii. The drug product is the subject of a notice of opportunity for hearing issued under Section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the Federal Register on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications; and
    iv. The drug product is presently the subject of an efficacy review study performed by FDA (see 21 CFR 310.6 including all subsequent amendments and supplements). The FDA efficacy review potentially can determine justification for a drug product's medical need. If a drug product fails this review, the product is classified as a DESI drug.
2. Reimbursement is not available for the purchase or administration of any drug product that is identical, related or similar, as defined in 21 CFR 310.6 (including all subsequent amendments and supplements), to a drug product that meets the conditions of (a) above.
3. The initial list of drugs and related drug products classified as "less than effective" by the FDA pending outcome of the NOOH appears

at 21 CFR 310.6. Subsequent revisions to this list which are adopted, shall appear in the Federal Register.

(b) To obtain a list of DESI drugs, see N.J.A.C. 10:51, Appendix A.

8:83C-1.23 Bundled drug service

(a) "Bundled drug service" means a drug or service that is marketed or distributed by the manufacturer or distributor as a combined package which includes in the cost the drug product and ancillary services such as, but not limited to, case management services and laboratory testing.

(b) Bundled drug service shall not be eligible for reimbursement by the PAAD program. The cost of the drug product which is a component of a bundled drug service (see N.J.A.C. 8:83C-1.14, Covered Pharmaceutical Services) shall be covered by the PAAD program.

1. In order to determine eligibility for reimbursement, manufacturers or distributors of a bundled drug service shall submit complete product information, including the cost to the PAAD program of the drug product component of the bundled drug service, and other information as requested by the Department, to the Commissioner, Department of Health and Senior Services, PO Box 360, Trenton, New Jersey 08625.

8:83C-1.24 Claim submission

(a) An approved pharmacy provider may choose to:

1. Submit a properly completed hard copy pharmacy claim form approved by the New Jersey Division of Medical Assistance and Health Services (DMAHS).
2. Submit an electronic media claim (EMC) by modem, diskette or magnetic tape in an electronic format approved by DMAHS.
    i. In order for a pharmacy provider to be eligible to submit an EMC claim to the Medicaid and/or PAAD programs, a pharmacy provider or vendor of EMC services shall complete the "New Jersey Medicaid Provider Electronic Billing Agreement."
    ii. The completed agreement shall be submitted to the fiscal agent and approved by the Division of Medical Assistance and Health Services.
    iii. The pharmacy provider or vendor of EMC services shall submit electronic media claims under an approved submitter

identification number and comply with EMC requirements contained in the EMC Manual, Appendix E, incorporated herein by reference.

iv. For the purposes of this subchapter, all electronically submitted claims, including POS claims, shall commonly be referred to as EMC claims; or

3. Enter into an agreement with a point-of-sale (POS) intermediary or directly provide a similar telecommunication network approved by DMAHS to submit claims to the fiscal agent for adjudication. POS claims require an electronic format which complies with the National Council Prescription Drug Program standards, Version 3.2, as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

i. The approved POS intermediary or provider established network shall enter into an agreement with the State of New Jersey to provide on-line telecommunication services, including transmission of pharmacy claim detail data, access to the fiscal agent's POS computer and return of adjudicated claim data to the provider.

(b) A properly completed claim form or a properly for matted electronic media claim (EMC) may be submitted to the fiscal agent, or transmitted by an approved POS intermediary or provider established telecommunication network to the fiscal agent for claims adjudication.

1. A single claim form shall be completed manually or by computer or an EMC claim shall be transmitted in the approved EMC format for each PAAD prescription dispensed. See N.J.A.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement for instructions concerning the completion and submission of the specified claim form, and NJ.A.C. 10:51, Appendix E, incorporated herein by reference, regarding the proper EMC claim format;

2. All claim forms and EMC claims must contain the National Drug Code (NDC) of the actual drug dispensed. The 11-digit NDC has three components. The first five digits are the manufacturer's labeler code, the next four digits are the product code, and the final two digits are the package size code. For claim submission, leading zeros shall be included in all fields. For example, 00003-0234-01.

i. The dispenser shall always report the actual labeler code and drug product code of the drug dispensed. The package size code reported on the claim.

3. All PAAD pharmacy claims submitted to the fiscal agent for payment consideration shall be adjudicated based on the outcome of established POS and PDUR edits, regardless of the mode of claim submission.

8:83C-1.25 Eligible PAAD beneficiary

(a) An applicant shall be determined to be eligible for Pharmaceutical Assistance to the Aged and Disabled only if physically present in New Jersey at the time of application and utilization, in accordance with the provisions of N.J.A.C. 8:83.

1. Benefits shall not be payable for patients in nursing facilities, hospitals or special hospitals by the PAAD program during any period recipients are covered for drug benefits by Medicaid, Medicare, Blue Cross and Blue Shield of New Jersey, Inc., or other insurance benefits or if such benefits are covered in the daily rate of the facility.

8:83C-1.26 PAAD beneficiary identification

(a) Pharmacies should verify that the beneficiary is a PAAD covered person. This is done by checking the beneficiary's PAAD identification card.

(b) The PAAD program shall issue to all PAAD eligibles a Validation Identification Care. The document shall contain the patient's name, PAAD identification number, effective date and expiration date.

(c) The beneficiary is eligible only for the period of time indicated on the identification card.

8:83C-1.27 Point-of-Sale (POS) claims adjudication system

(a) PAAD pharmacy claims may be submitted through a POS system and adjudicated by the State's fiscal agent online and in real-time. The POS system is an alternative to other methods of claim submission, including magnetic tape, diskette and paper claims. The pharmacist would be required to enter pharmacy claim detail data into a computer or POS device and transmit this data to the fiscal agent over a dedicated telephone line. Regardless of the method of claim submission, all claims will go through all New Jersey Medicaid Management Information System (NJMMIS) claims processing edits and the claims will be processed to determine their payment disposition (for example, paid or denied).

(b) In order for a PAAD approved pharmacy provider, in accordance with N.J.A.C. 8:33C-1.5, to submit pharmacy claims through a POS system, the provider shall enter into an agreement with a POS intermediary or shall directly

provide a similar telecommunications network approved by the New Jersey Division of Medical Assistance and Health Services.

1. In order to become an approved POS intermediary or provider established network, a firm shall notify the Division at the following address:

   Division of Medical Assistance and Health Services
   Office of Information Systems
   PO Box 712-Mail Code #4
   Trenton, New Jersey 08625-0712
   Telephone: (609) 588-2802

2. The Division shall send the interested party a summary of the program and instructions on how to submit an application.

3. The Division shall consider the following in evaluating an application:

   i. The applicant's general approach and plans to meet the requirements of the POS project;

   ii. The applicant's detailed approach and plans to meet the requirements of the POS project;

   iii. The applicant's documented qualifications, expertise, and experience on similar projects;

   iv. The applicant's proposed staff's documented qualifications, expertise, and experience on similar projects; and

   v. The applicant's adherence to the requirements of the Health Care Financing Administration.

(c) A POS participating pharmacy or intermediary must supply the computer hardware or POS device and required software to generate electronic media claims (EMC) in a format consistent with POS standards adopted by the PAAD program.

(d) A POS participating pharmacy or intermediary shall supply modem capability required to properly transmit claim detail data to the approved POS intermediary or to participate in the provider established telecommunication network.

(e) All PAAD pharmacy providers choosing to submit claims through the POS system, shall submit claims in the approved electronic format, and transmit these claims on-line for adjudication by the fiscal agent's POS computer system.

1. Pharmacy services provided to nursing facility and residential care residents utilizing 24 hour unit-dose or modified unit-dose drug delivery systems are precluded from the POS system.

(f) Claim data requirements for electronic media claims (EMC) generated by POS participating pharmacies include:

1. The first five alpha characters of the last name and the first three alpha characters of the PAAD beneficiary's first name;
2. The 12 digit PAAD identification number;
3. The date of birth, if applicable;
4. The date of service or dispense date;
5. The pharmacy prescription number;
6. The actual 11 digit National Drug Code (NDC) of the drug dispensed;
7. The metric quantity dispensed;
8. The days supply;
9. The prescriber's Medicaid provider service number;
10. The third party payment, if applicable;
11. The provider's usual and customary charge; and
12. The pharmacy provider number.

(g) Additional supplementary data requirements, which are claim specific, include:

1. The medical certification indicator;
2. The nursing facility residency indicator;
3. The compound drug indicator;
4. The other insurance indicator, if applicable; and
5. The carrier code(s), if applicable.

(h) A POS participating pharmacy or intermediary shall be required to implement software changes requested by the Division within 60 days of notification of such a request to ensure the generation of electronic claims acceptable to the PAAD program.

(i) Pharmacy software must have the capability to display on-line adjudicated claim data returned to the pharmacy by the fiscal agent, including:

1. Payment disposition;
2. Error code messages; and
3. Claim pricing data, including drug cost reimbursement, dispensing fee and applicable copayment amounts.

(j) Pharmacy software must provide the pharmacy with the capability of claim reversal and resubmission, if required.

1. A pharmacy may initiate a claim reversal of a previously submitted pharmacy claim for a period of 12 months from the initial date of claim service.
2. Pharmacies are required to initiate claim reversals for those services in which a claim was generated and adjudicated to payment by the fiscal agent's POS computer and the service was not subsequently provided to a PAAD beneficiary.
3. All prescriptions adjudicated to payment by the fiscal agent's computer shall be subsequently dispensed and their receipt by PAAD beneficiaries properly documented on a PAAD approved certification statement/signature log. (See N.JA.C. 10:49-9.6)

(k) Pharmacies are required to interact with prescribers and/or beneficiaries at POS to resolve matters related to on line messages resulting form claim adjudication by the fiscal agent.

8:83C-1.28 Prospective Drug Utilization Review (PDUR) program

(a) The Division of Medical Assistance and Health Services of the Department of Human Services and the Department of Health and Senior Services (DHSS) have established a prospective drug utilization review (PDUR) program to assist pharmacy providers in monitoring drug utilization by PAAD beneficiaries. As a component of the PAAD point-of-sale (POS) claims adjudication system, the State's fiscal agent will review drug utilization based on claims submitted on-line and provide pharmacists with responses in real-time regarding utilization within PDUR standards as recommended by the Drug Utilization Review (DUR) Board and approved by DHSS. Similar responses related to electronic media claims (EMC) or paper claims processed by the New Jersey Medicaid Management Information System (NJMMIS) shall be received by pharmacies on the Remittance Advice statement.

1. PDUR standards developed by the DUR Board shall be based on official compendia and accepted medical literature and shall include, but not be limited to, those standards established by First Data Bank (FDB) as part of the FDB DUR information system. The FDB standards are incorporated herein by reference and may be obtained from First Data Bank, The Hearst Corp., 1111 Bayhill Drive, San Bruno, CA 94066.

2. PDUR standards shall be applied to all PAAD pharmacy claims, regardless of the mode of claim submission.

(b) POS participating pharmacy providers shall be required to meet the conditions described in N.J.A.C.8:83C-1.27.

(c) In addition to POS responses related to adjudication of PAAD pharmacy claims returned to the pharmacy, pharmacists shall be notified regarding drug utilization inconsistent with adopted PDUR standards which may include, but not be limited to:

1. Drug interactions;

2. Maximum/minimum daily dosage alerts;

3. Therapeutic duplication;

4. Drug age conflicts;

5. Duration of therapy;

6. Drug-disease precautions; and

7. Drug-pregnancy precautions.

(d) The PDUR program may apply adopted standards based on a severity index approved by the DHSS or DUR Board to determine appropriate pharmacist intervention and/or claim disposition (for example, payment or denial) of PAAD pharmacy claims.

(e) Based on the severity of a potential PDUR conflict or interaction, pharmacists shall be required to consult with the beneficiary and/or prescriber to resolve matters indicated by PDUR messages returned by the POS system.

(f) The pharmacist intervention requirements related to the PDUR program are in addition to beneficiary interactions related to New Jersey State Board of Pharmacy requirements regarding the "offer to consult," as described in N.J.A.C. 13:39-7.14, Patient profile record system.

8:83C-1.29 Medical exception process (MEP)

(a) For pharmacy claims with service dates on or after May 3, 1999 that exceed DUR Board standards, the PAAD program shall utilize the medical exception process (MEP) to allow the override of a claim denial, when medically necessary.

1. The MEP may be administered by a vendor on behalf of DHSS.
2. All pharmacy claims shall be subject to the MEP regardless of claims media, except that claims from institutionalized beneficiaries shall be exempt from the PDUR and MEP until notice is issued otherwise.

(b) The MEP shall be as follows:

1. Upon the occurrence of a PDUR edit indicating that a claim is denied unless a medical exception override is applied, the pharmacist shall contact the MEP contractor.
2. The MEP contractor shall approve the claim for payment for the full prescription specified, or a 30-day supply of the prescription, whichever amount is less, unless it is clear that consumption of the prescribed medication poses a threat to the patient's life or may result in a potentially serious illness based on the information available to the pharmacist and the MEP contractor.
3. If the prescription exceeds a 30-day supply, the MEP contractor shall send the prescriber an MEP Prescnber Notification Letter form, along with the PAAD beneficiary's name and PAAD identification number, the dispense date, drug quantity and drug description, and the toll-free telephone number of the MEP contractor.
4. In order to request the medical exception override, the prescriber shall submit the completed MEP Prescriber Notification Letter to the MEP contractor with a justification for the medical exception override, and the anticipated length of time the medical exception override for the PAAD beneficiary will be necessary to satisfy the length of therapy required.
5. The MEP contractor shall render a decision on the request for the medical exception override documented in the completed MEP Prescriber Notification Letter, basing the decision whether to grant or deny the request upon drug standards and protocols established by the DUR Board, and shall notify the PAAD beneficiary, the prescriber and the pharmacist of the decision.

6. If the request is approved, the MEP contractor shall issue an authorization number recognized by the NJMMIS for the medical exception override to facilitate claim payment.

(c) Except as (b)2 above applies, the PAAD program shall deny payment for claims subject to the MEP process for which an authorization number has not been issued by the MEP contractor.

(d) PAAD beneficiaries, or prescribers acting with the consent of the PAAD beneficiary, and pharmacies (following receipt of a Remittance Advice Statement) may request a fair hearing to appeal a decision by the MEP contractor not to approve a claim pursuant to (b)2 or 5 above within 30 calendar days following the date of the claim denial, in accordance with N.J.A.C. 8:83-6.12.

1. The request for a fair hearing shall be made in writing, and shall specify the reasons the PAAD beneficiary, pharmacy or prescriber believes that the MEP's decision was incorrect.

2. The request for a fair hearing shall be submitted to:

PAAD MEP
PO Box 715
Trenton, NJ 08625-0715

8:83C-1.30 Drug rebate program

Reimbursement for legend drugs shall be limited to manufacturers who have entered into a PAAD rebate agreement with the Department of Health and Senior Services through the Division of Medical Assistance and Health Services pursuant to N.J.A.C. 10:51-1.22.